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EXAMINER
TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
1617	17

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/609,552	Applicant(s) Murray et al
	Examiner R.S. Travers J.D., Ph.D.	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 14-23, and 25-33* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 14-23, and 25-33* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The request for reconsideration, declarations and information disclosure statement filed June 20, 2003 have been received and entered into the file. Lacking a petition for special consideration required for an IDS received after an Official action on the merits, the presented information disclosure statement will not be considered.

Applicant's arguments filed June 20 2003 have been fully considered but they are not deemed to be persuasive.

Claims 1, 14-23 and 25-33 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required

undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines to what effect the "effective amount of Niacin" is directed. Although various effects are recited, collateral to constructive effect, Applicant fails to recite therapeutic effect desired. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compound amounts without undue experimentation. In the instant case, only a limited number of "effective amount of Niacin" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "effective amount of Niacin" dosages,

necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1, 14-23, and 25-33 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1, 14-23, and 25-33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 14-23, and 25-33 are rendered indefinite by the phrase and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining a medicament amount encompassing an "effective amount of Niacin" are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

> to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1, 14-21, 23, 24 and 26-33 are rejected under 35 U.S.C. § 103 as being unpatentable over Tang et al, Brown et al, in view of Murray et al, all of record.

Tang et al and Brown teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. Elevated ingestion levels of these (see especially Brown et al, page 430, paragraph 3) medicaments are taught as significantly decreasing the progression of HIV infected individuals to AIDS. Tang et al teach the greatest benefit was significantly correlated with the highest niacin intake levels. Claims 1, 14-21, 23, 24 and 26-33, and the primary reference, differ as to:

1) employment to the amide form.

2) the employment of these medicament as anti-HIV agents,

3) administration levels of the medicaments, and

4) concomitant employment of these medicaments.

Murray et al teach nicotinamide as the form employed in-vivo; with the conversion from niacin to nicotinamide in-vivo as a normal course of events in the liver.

Additionally, Murray et al teach nicotinamide, the physiologically employed form of niacin, as useful for inhibiting HIV in-vitro. Possessing this information, the skilled artisan would see the claimed niacin as an anti-HIV agent in-vivo, and view as obvious, the employment of this compound for treatment of HIV infections as obvious.

Tang et al, teaching high dietary niacin intake as associated with a positive clinical outcome for HIV infected patients, would have motived the skilled artisan to employ high niacin levels to treat HIV infections. Additionally, determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed HIV therapeutic methods

The instant claims are directed to effecting a biochemical pathway with an old and well known compound. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn

to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art dose not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two conventional anti-HIV agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of

achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed methods for increasing systemic tryptophan.

Claims 22 and 25 are rejected under 35 U.S.C. § 103 as being unpatentable over Tang et al, Brown et al, in view of Murray et al, all of record, as set forth above in further view of Rideout et al. .

Rideout et all teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for treating inflammation, viewed by the skilled artisan as immuno-suppressive. Claims 22 and 25, and the primary reference, differ as to:

1) the concomitant employment of these medicaments.

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-HIV agents. It would follow that the recited claims define prima

facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

RESPONSE TO ARGUMENTS

Declarations presented by the Doctors Murray and Sidebottom are unconvincing. Determinations of failure to enable under 35 USC 112, first paragraph; or clearly establish a claims metes and bounds under 35 USC 112 , second paragraph; or obviousness under 35 USC 103, flow from legal analysis, not scientific analysis. The presented declarations fail to establish as faulty, those elements central to the presented rejections. The instant claims are not enabled, and fail to establish identifiable metes and bounds because they lack a stated therapeutic goal. A method to increase systemic tryptophan is simply that: a method to increase systemic tryptophan. Thus, when systemic tryptophan is increased, the claim limitations are met. Perusal of the presented arguments leads Examiner to believes a somewhat narrower goal is envisioned in the instant application; yet limitations directing the claims to this unstated narrower goal are not present in the instant claims.

Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently

functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Examiner notes the presented claims are directed to "increasing systemic tryptophan", and thus, would be practiced by the administration of the claimed compounds wherein an effect was observed, as in the teaching of Tang et al, Brown et al and Murray et al.. As presented, the claims read on providing this response in any situation, regardless the desired outcome. Tang et al, Brown et al and Murray et al

administering the instant claimed compounds in situations encompassed by the instant claims, thus, obviating the use herein claimed.

Arguments presented to rebut the presented obviousness rejection are unconvincing. As stated above, the instant claims are directed to "increasing systemic tryptophan" and thereby directed to some slight change in the tryptophan levels, such as those set forth by administering niacin as taught by Tang et al, Brown et al and Murray et al. Applicants argue distinctions between those outcomes envisioned by Tang et al, Brown et al and Murray et al, and those therapies envisioned by Applicants in the instant specification; these arguments are not convincing. Examiner must examine the claims as presented, not as envisioned by Applicant. Limitations from the specification will not be, and can not be, read into the claims during examination. Thus, arguments based on unclaimed limitations are moot.

Tang et al, Brown et al and Murray et al teach administration of Applicants' compounds for a use recited in the instant claims, clearly providing a situation where this compounds would "increase systemic tryptophan", as herein claimed. Examiner notes the instant claims fail to outline a clear and definite therapeutic endpoint. Absent a clear minimal, or maximal, effect for practicing the instant claims, those claims presented read on any therapeutic benefit collateral to administration of the recited compound; such as those taught by Tang et al, Brown et al and Murray et al. Simply

stated, Examiner must examiner the claims as presented, and can not find convincing, arguments based on unclaimed limitations.

Applicants' rebuttal arguments constructively rely on numerous limitations not set forth in the instant claims. Simply stated, the Examiner cited prior art teaches a biochemical effect residing under the penumbra of outcomes recited by the instant claims. That those outcomes taught by Tang et al, Brown et al and Murray et al are not those envisioned by Applicant are not germane to the instant rejection. As stated above, the claims are examined to their full breath, and are not limited to only those outcomes envisioned by Applicants

Arguments provided to rebut the obviousness rejection are unconvincing. Examiner cited prior art teaches anti-HIV therapy by administering elevated levels of niacin. Those therapeutic goals set forth in the Examiner cited prior art differ from those herein claimed not at all. Possessing the Examiner cited prior art, the skilled artisan would have been motivated to administer elevated niacin levels and enjoyed an expectation of anti-HIV therapeutic success. Niacin, therapeutically administered was reported by the Examiner cited prior art as slowing the progression of the disease, and reducing symptomology. The skilled artisan would seen the niacin administration effects, and a therapeutic benefit as indistinguishable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the

shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617